

#20/E

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Hughes, Neil on July 08, 2003.

The application has been amended as follows:

a. Rewrite the claim 1 as follows:

FI
---- Claim 1 (currently amended) A ~~pharmaceutical~~ composition of microemulsion concentrate consisting essentially of a cyclosporin dissolved in a solvent system consisting of a fully acetylated monoglyceride lipophilic solvent having a minimum acetylation of 96%, a hydrophilic organic solvent and a synergistic mixture of two surfactants, wherein the microemulsion concentrate yields a droplet size in an emulsion of less than 2000 Å as

measured by light transmittance through a cell. ----

b. Claim 15. cancelled.

c. In claim 17, line 1, replace [claim 15] with --claim 1 ---- right before "wherein".

d. Claim 18. cancelled.

e. Rewrite the claim 19 as follows:

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F2
--- Claim ~~19~~³. (currently amended) The composition of claim 1 wherein said two surfactants are selected from a group consisting of one of which is a polyoxyethylene glycolated natural or hydrogenated vegetable oil and the second of which is a polyoxyethylene-sorbitan-fatty acid ester. ---

f. In claim 20, lines 1-2, replace [claim 15 further comprising a] with --claim 1 wherein the --- right before "hydrophilic" and insert --- is -- right before "miscible".

g. In claim 21, line 2, insert -- consisting --- right after "group".

h. In claim 22, lines 1-2, delete [at least] right before "two surfactants" and insert --- consisting --- right after "group".

i. Claims 23. cancelled.

f. Rewrite the claims 24-25 as follows:

F3
--- Claim ~~24~~⁷. (currently amended) A pharmaceutical composition of microemulsion concentrate consisting of cyclosporine, a fully acetylated monoglyceride having a minimum acetylation of 96%, propylene glycol, and a synergistic mixture of polyoxyl 40 hydrogenated castor oil and polyoxyethylene 20 sorbitan monolaurate. ---

--- Claim ~~25~~⁸. (currently amended) A pharmaceutical composition of microemulsion concentrate consisting of cyclosporine, a fully acetylated monoglyceride having a minimum acetylation of 96%, propylene carbonate, and a synergistic mixture of polyoxyl 40 hydrogenated castor oil and polyoxyethylene 20 sorbitan monolaurate. ---

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
July 15, 2003
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